UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,940	10/08/2004	Russell Heinrich	2776	7181

7590 09/29/2009

Covidien
60 Middletown Avenue
North Haven, CT 06473

EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	PAPER NUMBER
3734	
MAIL DATE	DELIVERY MODE
09/29/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/510,940	HEINRICH ET AL.	
	Examiner	Art Unit	
	KATHERINE M. DOWE	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *12-69* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 70-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 9, 2009 has been entered.

2. Claims 1-72 are currently pending, with claims 12-69 withdrawn from consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-11 and 70-72 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient support in the disclosure for the limitation, "a plurality of micro-electromechanical system (MEMS) devices disposed along an entire length of the surgical instrument" (lines 3-4 of claim 1).

The MEMS devices are discrete elements spaced apart along the length of the device, and thus there is no support for the MEMS devices disposed along an entire length of the device. There are portions of the device that do not have a MEMS device attached.

Additionally, there is insufficient support for the limitation, "at least one of the MEMS devices is a two or three dimensional acceleration measuring device for determining the position of the surgical instrument relative to target tissue" (lines 9-10 of claim 1). The specification recites, "When accelerometer MEMS devices "M" are employed and suitably integrated as two or three orthogonal assemblies, they effectively constitute a two-dimensional or three-dimensional acceleration measuring device or gyroscope when provided with a known point of origination and appropriately configured computer system" (page 22, lines 8-11). Thus, support only exists for a plurality of MEMS devices integrated together to form the two- or three- dimensional acceleration measuring device. One MEMS device, which is defined as "a single integral device that is operationally independent of other MEMS devices" (lines 7-8 of claim 1), is not capable of being a two- or three- dimensional acceleration measuring device.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-11 and 70-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what Applicant is claiming with

the limitation, "a plurality of micro-electromechanical system (MEMS) devices disposed along an entire length of the surgical instrument". The disclosure indicates the MEMS devices are discrete elements placed at discrete locations spaced along the device and do not cover an entire length of the device. For the purpose of examination, the Examiner is interpreting the limitation such that the discrete locations of the MEMS devices are located at discrete points which may be any point along the entire length of the device including points at the proximal, middle, and distal ends of the device.

Additionally, it is unclear how "at least one of the MEMS devices is a two or three dimensional acceleration measuring device for determining the position of the surgical instrument relative to target tissue" (lines 9-10 of claim 1). The specification recites, "When accelerometer MEMS devices "M" are employed and suitably integrated as two or three orthogonal assemblies, they effectively constitute a two-dimensional or three-dimensional acceleration measuring device or gyroscope when provided with a known point of origination and appropriately configured computer system" (page 22, lines 8-11). Thus, support only exists for a plurality of MEMS devices integrated together to form the two- or three- dimensional acceleration measuring device. One MEMS device, which is defined as "a single integral device that is operationally independent of other MEMS devices" (lines 7-8 of claim 1), is not capable of being a two- or three-dimensional acceleration measuring device.

Regarding claim 6, it is unclear how "*each* of the plurality of MEMS devices is configured and adapted to measure distance between the tissue contacting surface of the staple cartridge assembly and the tissue contacting surface of the anvil" (lines 2-3 of

claim 6) when at least one MEMS device is configured as an acceleration measuring device and the plurality of MEMS devices is disposed along an entire length of the surgical instrument (claim 1). It is unclear how an acceleration measuring MEMS device may measure distance between the tissue contacting surfaces and it is unclear how a MEMS device located in the handle assembly may measure distance between the tissue contacting surfaces. The Examiner suggests amending the language to recite "at least a second MEMS device" instead of "each of the plurality of MEMS devices".

7. Claim 8 recites the limitation "the tissue clamped between the tissue contacting surface[s]" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim. Antecedent basis merely exists for tissue that is engaged by the end effector (claim 1); however, tissue engaged by the end effector is not necessarily tissue clamped between the tissue contacting surfaces of the staple cartridge and the anvil.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Lebouitz et al. (US 6,972,199). Lebouitz et al. disclose an end effector (Fig 3) configured and adapted to engage tissue; and a plurality of micro-electromechanical system (MEMS) devices (individual sensors forming sensor array 45) disposed along an entire length of the surgical instrument (which is defined merely as the end effector in claim 1) for

sensing a condition (col 5, ll 29-38). Each MEMS device is a single integral device that is operationally independent of other MEMS devices configured to communicate with the surgical instrument. At least one of the MEMS devices is a two or three dimensional acceleration measuring device for determining the position of the surgical instrument relative to target tissue (col 2, ln 56 –col 3, ln 13 and col 3, ll 31-41). At least one control operation of the surgical instrument is automatically adjusted based on feedback received from the at least one MEMS device via at least one comparator for comparing at least one of a second condition and a measured parameter against at least one of a predetermined value (col 7, ll 3-17).

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims 1-10, 71, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooven (US 5,518,163) in view of Wang et al. (US 2004/023652) and Lebouitz et al. (US 6,972,199). Hooven discloses the invention substantially as claimed including a surgical stapler (Fig 2) comprising a handle assembly (40), an elongate member (41), and an end effector (42). The end effector (Fig 6) comprises a staple cartridge assembly (74) and an anvil (75) operatively associated with the staple cartridge. The staple cartridge and anvil each have tissue contacting surfaces for engaging tissue therebetween. The device comprises a plurality of sensors, or MEMS devices (including 163 and 164 in Figure 17), to transmit various types of information

during the operation of the instrument including the movement of the various elements used to drive the staples into the tissue, sense whether or not the appropriate tissue is in the appropriate position, and physical parameters of the surrounding environment such as blood oxygen content, tissue density of adjacent tissue or various hemostasis characteristics of adjacent tissue (col 6, ll 25-48; col 7, ll 43-50). The sensors, or MEMS devices, are connected to a microprocessor/controller to automatically adjust the control of at least one operation of the surgical instrument based on feedback from the MEMS device via a comparator for comparing at least one of a second condition and a measured parameter against at least predetermined value (col 8, ll 21-50).

Hooven discloses all the sensors, or MEMS devices, are connected to a microprocessor/controller (203) via an interface cable (205) (col 8, ll 36-37) and that many contacts and sensors may be located in the handle portion of the instrument so that the end effector, or head end, of the instrument may be kept as small as possible (col 6, ll 26-30). However, Hooven does not specifically disclose the MEMS devices are disposed along an entire length of the surgical instrument including the handle assembly, the elongate member, and the end effector. Wang et al. discloses a robotic surgical instrument and teaches several sensors, or MEMS devices (172, 178, 182), are disposed at various joints of the device to provide position information during use of the surgical instrument (¶0024; Figures 2-3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Hooven such that each joint additionally comprised position sensors, or MEMS devices,

to provide the user with precise information about the movement of the end effector and/or elongate member with respect to the handle and/or the patient.

Additionally, Hooven does not disclose at least one of the MEMS devices is a two or three dimensional acceleration measuring device for determining the position of the surgical instrument relative to target tissue. Lebouitz et al. disclose a surgical instrument comprising a plurality of sensors, or MEMS devices (individual sensors forming sensor array 45). Lebouitz et al. teach at least one of the MEMS devices is a two or three dimensional acceleration measuring device for determining the position of the surgical instrument relative to target tissue (col 2, ln 56 –col 3, ln 13 and col 3, ll 31-41). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Hooven and Wang et al. such that at least one of the MEMS devices comprised a two- or three- dimensional acceleration measuring device to provide the user with precise information about the movement of the surgical instrument with respect to the target tissue.

12. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hooven (US 5,518,163), Wang et al. (US 2004/023652) and Lebouitz et al. (US 6,972,199), as applied to claim 9 above, further in view of Racenet et al. (US 2004/0267310). Hooven, Wang, and Lebouitz disclose the invention substantially as claimed as shown above. However, Hooven discloses the device is a linear stapler capable of performing an endoscopic gastrointestinal anastomosis and does not disclose the device is an annular stapler. Racenet et al. disclose a similar surgical stapler and teach the stapler may

either be linear (Figure 15) or annular (Figure 19) depending on the desired surgical procedure. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Hooven, Wang et al., and Lebouitz et al. such that the anvil and cartridge were designed as an annular stapler according to the teachings of Racenet et al. such that the device may more readily perform an end-to-end anastomosis.

Response to Arguments

13. Applicant's arguments with respect to claims 1-11 and 70-72 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
September 23, 2009

/K. M. D./
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734